Minute Order Form (06/97)

United States District Court, Northern District of Illinois

Name of Assigned Judge or Magistrate Judge	Rebecca R. Pallmeyer	Sitting Judge if Other than Assigned Judge	
CASE NUMBER	01 C 8452	DATE	9/7/2004
CASE TITLE	Dr. Sakharam D. Mahurkar vs. C.R. Bard, Inc., et al		

[In the following box (a) indicate the party filing the motion, e.g., plaintiff, defendant, 3rd party plaintiff, and (b) state briefly the nature of the motion being presented.]

MOTION:

DOCKET ENTRY:

(1) ☐ Filed motion of [use listing in "Motion" box above.]

(2) ☐ Brief in support of motion due _____.

(3) ☐ Answer brief to motion due_____. Reply to answer brief due_____.

(4) ☐ Ruling/Hearing on _____ set for _____ at _____.

(5) ■ Status hearing set for 10/6/2004 at 9:00 A.M..

(6) ☐ Pretrial conference[held/continued to] [set for/re-set for] on _____ set for _____ at _____.

(7) ☐ Trial[set for/re-set for] on _____ at _____.

(8) ☐ [Bench/Jury trial] [Hearing] held/continued to _____ at _____.

(9) ☐ This case is dismissed [with/without] prejudice and without costs[by/agreement/pursuant to]
☐ FRCP4(m) ☐ Local Rule 41.1 ☐ FRCP41(a)(1) ☐ FRCP41(a)(2).

(10) ■ [Other docket entry] Enter Memorandum Opinion And Order. Defendants' motion for summary judgment of noninfringement of the '561 Patent (Doc. No. 180-1) is granted. Plaintiff's motion for summary judgment on literal infringement of the '561 Patent (Doc. No. 223-1) is denied. Plaintiff's motion for summary judgment on Defendants' licensee affirmative defense (Doc. No. 166-1) is granted but his motion for summary judgment on Defendants' invalidity defense to the '155 Patent (Doc. No. 169-1) is denied. Defendants' motion to bar expert testimony (Doc. No. 187-1) is granted but their motion to strike Plaintiffs "supplemental" report (Doc. No. 187-2) is denied. Defendants supplemental expert report is due October 15, 2004.

(11) ☐ [For further detail see order (on reverse side of/attached to) the original minute order.]

	No notices required, advised in open court.		3 number of notices	Document Number
	No notices required.			
✓	Notices mailed by judge's staff.		SEP 08 2004 date docketed	284
	Notified counsel by telephone.			
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UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

DR. SAKHARAM D. MAHURKAR, Plaintiff,	)	
v.	)	No. 01 C 8452
C.R. BARD, INC., BARD ACCESS SYSTEMS, INC. and BARD HEALTHCARE, INC., Defendants.	)	Judge Rebecca R. Pallmeyer

MEMORANDUM OPINION AND ORDER

Plaintiff Dr. Sakharam D. Mahurkar is a nephrologist and inventor of catheters used in hemodialysis. Dr. Mahurkar holds several patents for catheters and related equipment, which he vigorously defends in the federal courts. In this case, Dr. Mahurkar charges Defendants C.R. Bard, Inc., Bard Access Systems, Inc. and Bard Healthcare, Inc. with infringing two of his patents under 35 U.S.C. §§ 271(a), (b), and (c): U. S. Patent No. 4,808,155 (the "'155 patent") for a "Simple Double Lumen Catheter" and U.S. Patent No. 4,895,561 (the "'561 patent") for the "Dual Lumen Catheter Connecting System." In his Second Amended Complaint filed on August 26, 2002, Dr. Mahurkar alleges that Defendants make, use, import, distribute, sell, and/or offer for sale a number of infringing products, including pre-curved Softcell, Optiflow, Hemoglide, Niagara, Niagara SlimCath, and Flexxicon II catheter assemblies. The court held a *Markman* hearing in December 2002 and has construed the claims in both patents. *See Mahurkar v. C.R. Bard, Inc.*, No. 01 C 8452, 2003 WL 21078033 (N.D. Ill. May 13, 2003) ("*Mahurkar I*"), *aff'd on reconsideration*, 2003 WL 22844237 (N.D. Ill. Dec. 1, 2003) ("*Mahurkar II*"). The parties have since filed a litany of motions.

At issue here are Defendants' Motion for Summary Judgment of Noninfringement of the '561 Patent, Plaintiff's Motion for Summary Judgment on Literal Infringement of the '561 Patent,

Plaintiff's Motion for Summary Judgment on Defendants' Licensee Affirmative Defense, Plaintiff's Motion for Summary Judgment on Defendants' Invalidity Defense to the '155 Patent, and Defendants' Motion to Bar Expert Testimony and Strike Plaintiff's "Supplemental" Report. For the reasons explained below, the motions are granted in part and denied in part.

BACKGROUND

The procedural history of the case leading to the *Markman* hearing, the background of the '155 and '561 patents, and the prior litigation between the parties were described in this court's May 13, 2003 and December 1, 2003 Memorandum Opinions and Orders. *See Mahurkar I*, 2003 WL 21078033, at *1-3, and *Mahurkar II*, 2003 WL 22844237, at *1. This opinion assumes the reader's familiarity with these earlier decisions and will summarize the relevant facts here only briefly.

The role of kidneys in the body is to remove toxins from the blood. When kidneys fail to function properly due to disease or injury, blood must be cleansed externally in a process called hemodialysis, which involves removing blood from a patient, diverting it to a blood treatment unit where it is cleansed, and then returning it to the patient. *Mahurkar v. Arrow Int'l, Inc.*, 160 F. Supp. 2d 927, 930 (N.D. Ill. 2001); *Mahurkar I*, 2003 WL 21078033, at *1. Hemodialysis catheters are devices that are inserted into a patient's vein for removal and return of blood. *Arrow Int'l*, 160 F. Supp. 2d at 930. The patents and products at issue in this case concern "double lumen" catheters for use in hemodialysis, that is, catheters having two separate lumens, or channels, one for removing uncleansed blood and one for returning cleansed blood. *Mahurkar I*, 2003 WL 21078033, at *1.

DISCUSSION

I. Motion for Summary Judgment as to `561 Patent

Both parties have moved for summary judgment with respect to the `561 patent. Dr. Mahurkar claims that the pre-curved Softcell, Optiflow, Hemoglide, Niagara, Niagara SlimCath, and Flexxicon II catheters (the "accused products") all literally infringe the `561 patent because they have "dual-lumen catheters" and "connecting means" which satisfy the elements of Claim 34 of the `561 patent. Defendants insist that their products do not infringe the `561 patent, either literally or under the doctrine of equivalents. The court considers each motion below.

A. Background

Patients suffering from chronic kidney failure require long-term hemodialysis, including blood cleansing several times a week for the remainder of their lives or until they receive compatible kidney transplants. *Mahurkar I*, 2003 WL 21078033, at *2. To limit puncture damage caused by inserting a new catheter during each treatment, chronic patients usually retain the same catheter in their bodies for a period of several weeks. Unless properly configured, the catheter, especially its tip, can cause extensive pain and trauma to a patient's vein during its extended residence. *Id.*

Prior to the invention of the `561 patent, extension tubes on catheters were generally straight. When straight catheters were placed in certain veins, such as the jugular vein in the neck, the extension tubes protruded awkwardly above a patient's shoulder, or towards the patient's ear. These straight catheters were uncomfortable and had a tendency to become dislodged during use or create additional trauma in the vein during extended residence. *Id.* (*See also* `561 patent, Ex. A to Pl. `561 Facts, col. 1, line 21 to col. 2, line 31.)[1] Dr. Mahurkar's `561 patent, issued on

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[1] The Local Rule 56.1 Statement of Undisputed Facts in Support of Plaintiff's Motion for Summary Judgment on Literal Infringement of the `561 Patent is cited as "Pl. `561 Facts ¶ __."

January 23, 1990, addressed this risk by bending a portion of the catheter assembly that remains outside the patient's vein so that the catheter could be "positioned in convenient anatomical sites during the periods between successive treatments to avoid patient discomfort and accidental displacement of the catheter." *Id.* (quoting `561 Patent, Ex. B to Second Amended Complaint, col. 1, lines 13-16); (Pl. `561 Facts ¶¶ 2-5, 39; Def. `561 Fact Resp. ¶¶ 2-5, 39.)[2]

1. Claim Construction of the `561 Patent

As noted, the court held a *Markman* hearing in December 2002 and has construed the disputed claims in the `561 patent. At issue here is Claim 34, which states:

> A dual-lumen catheter assembly comprising:
> a dual lumen catheter, and connecting means attached to the proximal end of said catheter and forming a pair of internal passageways which communicate at one end thereof with the dual lumens in said catheter, said passageways curving back toward the distal end of said catheter so that forces exerted on said connecting means at the other ends of said passageways will tend to move said catheter in the same direction as[3] said exerted forces.

(`561 Patent, col. 11, lines 14-23.) Claim 36, which is dependent upon Claim 34, also states: "The catheter assembly of claim 34 wherein each of said curved passageways is U-shaped." (*Id.*, col. 11, lines 31-32.)[4] The parties disputed the meaning of two terms in these Claims: "catheter" and "connecting means." The court found that "catheter" as used in the `561 patent means "a tubular device for withdrawing fluids from, or introducing fluids into, a cavity of the body, such as a blood vessel." *Mahurkar I*, 2003 WL 21078033, at *8. The catheter extends "from the distal end,

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[2] Defendants' Response to Plaintiff's Local Rule 56.1 Statement of Undisputed Facts in Support of Plaintiff's Motion for Summary Judgment on Literal Infringement of the `561 Patent is cited as "Def. `561 Fact Resp. ¶ __."

[3] The patent reads "in a direction opposite that of" said exerted forces, but the day the patent was issued, Dr. Mahurkar submitted a Certificate of Correction changing the language to "the same direction as." *Mahurkar I*, 2003 WL 21078033, at *8 n.9.

[4] *See* Illustration in `561 Patent, Ex. A to Appendix of Drawings.

the end that is first inserted into the patient's body, to the proximal end, where the connecting means attaches the catheter to the remainder of the apparatus." *Id.*

The court determined that "connecting means" is a means-plus-function clause. Pursuant to 35 U.S.C. § 112 ¶ 6, a claim element "may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof." Claim elements written in this format are construed to cover the corresponding structures described in the specification, and equivalents thereof. *Id.* The court therefore identified the corresponding structures disclosed in the specification that are linked or associated with the function. *Chiuminatta Concrete Concepts, Inc. v. Cardinal Indus., Inc.*, 145 F.3d 1303, 1308 (Fed. Cir. 1998). Specifically, the court found that the "connecting means" may be "(1) a Y-shaped connector connected to extension tubes that curve back toward the distal end of the catheter, and equivalents thereof; [or] (2) a unitary connecting member forming two internal U-shaped passageways, each of which is in communication with one of the lumens of the catheter, and equivalents thereof." *Mahurkar I*, 2003 WL 21078033, at *10. "[T]he proximal end of the catheter tube is straight and is attached either to the Y-shaped connector or the unitary connecting member, which can be curved." *Id.* "[T]he catheter itself must be visibly attached to a distinct portion, the connecting means, and the catheter tube must be straight, not curved." *Id.* In addition, the connecting means "must be something physically separate from the catheter." *Id.*

On reconsideration, the court confirmed that "the proximal end of the dual-lumen catheter, and the endpoint of the catheter itself, is the point where the two lumens end." *Mahurkar II*, 2003 WL 22844237, at *5. The `561 patent defines lumens as follows: "[d]ual-lumen hemodialysis catheters are normally supplied with certain auxiliary components permanently pre-attached to the catheter. These auxiliary components facilitate the connection of the two lumens of the catheter (which are extremely small within the catheter) to a pair of long flexible tubes which carry blood to and from the hemodialysis unit." *Id.* The court explained that "the lumens end at the point where

they are connected to the auxiliary components" and, thus, at the endpoint of the catheter itself. *Id.*

2. The Accused Products

As noted, Mahurkar charges that six of Defendants' products infringe the '561 patent. The court begins by describing the accused products, of which five (the "Softcell Group") are structurally similar, and a sixth, the Flexxicon II, is of a different design.

a. Softcell, Optiflow, Hemoglide, Niagara, and Niagara SlimCath

The Softcell, Optiflow, Hemoglide, Niagara, and Niagara SlimCath catheters (the "Softcell Group") all have (1) a catheter tube, (2) a Y-connector, and (3) two straight extension tubes.[5] (Def. '561 Facts ¶ 5.)[6] The catheter tubes of the Softcell Group have two lumens – a "return" lumen and an "intake" lumen, which are side-by-side within the catheter tubing. (*Id.* ¶¶ 6.) According to Defendants, the lumens continue through a curved portion of the apparatus which is still part of the "catheter," and end at a Y-connector which is a separate, auxiliary component that is physically attached to the proximal end of the catheter tube. (*Id.* ¶¶ 7, 8.) Dr. Mahurkar, on the other hand, asserts that the lumens end where the separate "curved tubular portion" begins, not at the Y-connector. He notes that in construing Claim 34, the court determined that the proximal end of the catheter tube is straight. In his view, if the catheter tube must be straight, so must the lumens. Dr. Mahurkar acknowledges that the Softcell Group catheters have a Y-connector that is part of the "connecting means," but he claims that in Softcell Group catheters, "the Y-connector is distanced

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[5] The Softcell, Optiflow, Hemoglide, Niagara, and Niagara SlimCath catheters all have a similar construction, as depicted in Ex. B to Appendix of Drawings.

[6] Defendants' Local Rule 56.1(a)(3) Statement of Uncontested Material Facts in Support of Motion for Summary Judgment of Non-Infringement of the '561 Patent is cited as "Def. '561 Facts ¶ __."

from the catheter tube by the portion of the connecting means including the preformed curve." (Pl. '561 Fact Resp. ¶¶ 7, 8.)[7]

For purposes of summary judgment, there is no dispute that during the manufacturing process for the Softcell Group, a curve is induced in a continuous piece of catheter tubing using curving mandrels[8] for each of the lumens, a curving fixture, and a heat source. (Def. '561 Facts ¶¶ 10, 12.) External components, such as "cuffs," "suture wings," and "suture wing retainers" are added to the outside of the tubing during the manufacturing process but are not part of the tube itself. (*Id.* ¶¶ 13, 14; Pl. '561 Fact Resp. ¶¶ 13, 14.)

b. Flexxicon II

The Flexxicon II catheter has a co-axial body with two concentric tubes enclosing two internal lumens that act as channels for blood flow. (Def. '561 Fact Resp. ¶ 38.) In other words, the "intake" and "return" lumens are not side-by-side as in the Softcell Group catheters, but instead consist of a small inner tube within a larger outer tube.[9] (Def. '561 Resp., at 4.)[10] The inner tube is formed from a single, pre-curved piece of tubing that runs continuously from the distal end to the Y-hub. Thus, the channel of the inner tube stretches uninterrupted from the distal end, through a pre-curved portion of tubing, to the Y-hub. (Def. '561 Fact Resp. ¶¶ 39, 41.) The outer tube, on the other hand, is manufactured by bonding two sections of tubing together approximately where the catheter tubing begins to curve. The bonding is so smooth, however, that it does not interrupt

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[7] Plaintiff's Response to Defendants' Local Rule 56.1(a)(3) Statement of Uncontested Material Facts in Support of Motion for Summary Judgment of Non-Infringement of the '561 Patent is cited as "Pl. '561 Fact Resp. ¶ __."

[8] A "mandrel" is "a metal bar that serves as a core around which material (as metal) may be cast, molded, forged, bent, or otherwise shaped." MERRIAM WEBSTER'S COLLEGIATE DICTIONARY 707 (10th ed. 1997).

[9] *See* Flexxicon II catheter, Ex. C to Appendix of Drawings.

[10] Defendants' Opposition to Plaintiff's Motion for Summary Judgment on Literal Infringement of the '561 Patent is cited as "Def. '561 Resp., at __."

the blood flow through the outer channel, which runs continuously from the distal end, through the curved segment, to the Y-hub. (*Id.* ¶¶ 42, 43.)

B. Standard of Review

Summary judgment is proper when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law." FED. R. CIV. P. 56(c). In determining whether there is a genuine issue of fact, the court must view the evidence and draw all reasonable inferences in favor of the party opposing the motion. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). Summary judgment on the issue of literal infringement is proper "when no genuine issue of material fact exists, in particular, when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device." *Goldenberg v. Cytogen, Inc.*, 373 F.3d 1158, 1163-64 (Fed. Cir. 2004) (quoting *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir. 1998)).

Determination of patent infringement requires a two-step analysis: (1) construction of the meaning and scope of the claims, and (2) comparison of the allegedly infringing device to the construed claim. *Novartis Pharmaceuticals Corp. v. Eon Labs Mfg., Inc.*, 363 F.3d 1306, 1308 (Fed. Cir. 2004). "Literal infringement of a § 112 ¶ 6 claim requires that the relevant structure in the accused device perform the identical function recited in the claim and be identical or equivalent to the corresponding structure in the specification." *Lockheed Martin Corp. v. Space Systems/Loral, Inc.*, 324 F.3d 1308, 1320 (Fed. Cir. 2003). Two structures may be "equivalent" under § 112 ¶ 6 if "they perform the identical function, in substantially the same way, with substantially the same result." *Kemco Sales, Inc. v. Control Papers Co.*, 208 F.3d 1352, 1364 (Fed. Cir. 2000).

An accused product that does not literally infringe a patent may nonetheless be infringing under the doctrine of equivalents. Unlike "equivalents" under § 112 ¶ 6, "equivalents under the doctrine of equivalents need only perform a substantially similar function" and not an identical function. *Kemco Sales*, 208 F.3d at 1364. Summary judgment of non-infringement is appropriate where no reasonable jury could find that an accused device "performs the identical function with the same structure, materials, or acts described in the specification or an equivalent thereof." *IMS Technology, Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1430 (Fed. Cir. 2000).

C. Analysis

Dr. Mahurkar claims that the accused products all have "dual-lumen catheters" and "connecting means" which satisfy the elements of the '561 patent. As noted, the court construed "connecting means" to be "(1) a Y-shaped connector connected to extension tubes that curve back toward the distal end of the catheter, and equivalents thereof; [or] (2) a unitary connecting member forming two internal U-shaped passageways, each of which is in communication with one of the lumens of the catheter, and equivalents thereof." *Mahurkar I*, 2003 WL 21078033, at *10. The parties agree that the accused products do not include connecting means defined by a Y-connector fastened to bent extension tubes. (Def. '561 Facts ¶ 15; Pl. '561 Fact Resp. ¶ 15; Def. '561 Fact Resp. ¶ 46.) Thus, infringement must be determined with reference to whether the accused products have a dual-lumen catheter and a "unitary connecting member" as described in the patent. *Mahurkar I*, 2003 WL 21078033, at *10.

1. Literal Infringement

Dr. Mahurkar argues that the accused products all have "dual-lumen catheters" that extend from "the distal tip of the catheter to the distal end of the curved portion of the assembly, or in other

words the point where the catheter assembly begins to bend." (Pl. '561 Mem., at 8.)[11] In his view, the point where the catheter tubing begins to bend is also the point where the "connecting means" begins; that is,

> the curved tubular portion of the catheter assembly (the unitary connecting member) forms a pair of internal passageways that communicate at one end thereof (the distal end) with the dual lumens of the straight catheter portion, the passageways curving back towards the distal end of the catheter so that forces exerted on the unitary connecting member at the other ends of the passageways will tend to move the catheter in the same direction as the exerted forces – exactly as required under claim 34 of the '561 patent.

(*Id.* at 10.) Defendants claim that the "catheter" portion of the accused products extends from the distal end that is inserted into the patient all the way around the curved tubular portion to the Y-connector. According to Defendants, the Y-connector with the straight extension tubes alone forms the "connecting means." The court addresses the Softcell Group and Flexxicon II catheters separately given their differing structures.

a. Softcell Group

Dr. Mahurkar's argument in support of literal infringement is based in part on the court's determination that "the catheter tube must be straight, not curved." *Mahurkar I*, 2003 WL 21078033, at *10. Contrary to Dr. Mahurkar's suggestion, this conclusion does not mean that all catheter tubes, including the catheter tubes in the accused products, must be straight without any curving portions. The court merely construed the term "catheter" as claimed in the '561 patent. *See, e.g., Optical Disc Corp. v. Del Mar Avionics*, 208 F.3d 1324, 1333 (Fed. Cir. 2000) ("the claim scope is determined without regard to the accused device"). Thus, the fact that the Softcell Group products have a straight tubular segment that continues around a curved segment does not preclude a finding that the entire length of tubing in those products is "catheter." Indeed, the continuous nature of the tubing weighs in favor of such a conclusion. As the court explained in

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[11] Plaintiff's Memorandum in Support of Summary Judgment on Literal Infringement of the '561 Patent is cited as "Pl. '561 Mem., at __."

Mahurkar I, "the catheter itself must be visibly attached to a distinct portion, the connecting means," which "must be something *physically separate from* the catheter." 2003 WL 21078033, at *10 (emphasis added).

Dr. Mahurkar insists that the straight portion of the tubing is "physically separate" from, and visibly and distinctly attached to, the curved portion of the tubing. (Pl. `561 Resp., at 13-14.)[12] His reasoning, however, is circular and inconsistent with the court's claim construction. Dr. Mahurkar argues that "[t]he catheter and the connecting means are visibly attached by the simple fact that there is no visible detachment between the two elements" and, at the same time, that the catheter (i.e., the straight tubular segment) is "physically separate and distinct from" the unitary connecting member (i.e., the curved tubular segment) because one is straight and the other is curved. (*Id.*) Dr. Mahurkar has not cited any authority for the proposition that a continuous piece of tubing becomes "physically separate" at some point where the tubing begins to curve. The court made clear in its *Markman* opinion that as claimed in the `561 patent, the catheter and the connecting means must be separate and distinct structures; in the court's view, a continuous, curved tube does not literally satisfy this requirement.

Dr. Mahurkar's interpretation is also inconsistent with the court's conclusion that "the proximal end of the dual-lumen catheter, and the endpoint of the catheter itself, is the point where the two lumens end." *Mahurkar II*, 2003 WL 22844237, at *5. The patent defines "lumens" as follows: "[d]ual-lumen hemodialysis catheters are normally supplied with certain auxiliary components permanently pre-attached to the catheter. These auxiliary components facilitate the connection of the two lumens of the catheter (which are extremely small within the catheter) to a pair of long flexible tubes which carry blood to and from the hemodialysis unit." *Id.* The "extremely

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[12] Plaintiff's Memorandum in Opposition to Defendants' Motion for Summary Judgment of Non-Infringement of the `561 Patent is cited as "Pl. `561 Resp., at __."

small" lumens in the accused products continue to the Y-connector, not merely to the point where the catheter tubing begins to bend.

The court finds that no reasonable jury could conclude that the Softcell Group catheters have an identical structure that literally infringes the '561 patent. Thus, Dr. Mahurkar's motion for summary judgment on this issue is denied and Defendants' corresponding motion for summary judgment is granted. *See Lockheed Martin*, 324 F.3d at 1318 (summary judgment is proper if "no reasonable jury could return a verdict for the nonmoving party"). To the extent the parties seek summary judgment on the issue of literal infringement based on "equivalent" structure, the court addresses the arguments below.

b. Flexxicon II

As described above, the Flexxicon II has a different construction than the Softcell Group catheters; specifically, the lumens of the Flexxicon II catheter are not side-by-side as in the Softcell Group catheters, but consist of a small inner tube within a larger outer tube. (Def. '561 Resp., at 4.) The inner tube is formed from a single, pre-curved piece of tubing that runs continuously from the distal end to the Y-hub. (Def. '561 Fact Resp. ¶¶ 39, 41.) The outer tube, however, is manufactured by bonding two sections of tubing together approximately at the point where the catheter tubing begins to curve. The bonding does not interrupt the blood flow through the outer channel, but the outer tube is not comprised of a single, "continuous" piece of tubing. (*Id.* ¶¶ 42, 43.) Defendants did not initially seek summary judgment of non-infringement as to the Flexxicon II due to this structural difference. (Def. '561 Mem., at 1 n.1.)[13] In response to Dr. Mahurkar's motion for summary judgment, they now claim that summary judgment is appropriate as to this product as well.

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[13] Defendants' Memorandum in Support of Motion for Summary Judgment of Noninfringement of the '561 Patent is cited as "Def. '561 Mem., at __."

Defendants argue that "no portion of the Flexxicon II could be a 'unitary connecting member' because the Court's construction requires that a 'unitary connecting member' form 'two internal [U-shaped] passageways, each of which is in communication with one of the lumens of the catheter.'" (Def. `561 Resp., at 9) (quoting *Mahurkar I*, 2003 WL 21078033, at *9). In Defendants' view, the fact that the inner tube continues unbroken through the straight and curved portions of the tubing prevents a conclusion that it "communicates" with any connecting member at the point where the two-piece outer tube is joined together. (*Id.*) Thus, Defendants say, the Flexxicon II has at most one internal passageway in communication with one separate lumen, and not two as required by the court's claim construction. (*Id.*) Dr. Mahurkar insists that such manufacturing distinctions are irrelevant to the literal infringement analysis because all of the catheters have a curved connecting means at the point where the straight catheter begins to bend. (Pl. `561 Reply, at 8.)[14]

To the extent Dr. Mahurkar's rationale for literal infringement by the Flexxicon II is based on his belief, described earlier, that a catheter can only be straight and, thus, any curved portion of tubing must be part of the connecting means, for the reasons stated, it is unavailing and does not support summary judgment in his favor. At the same time, it is undisputed that the outer tube of the Flexxicon II is separately connected to a distinct segment of tubing at the point where the catheter begins to bend. Whether this is sufficient to render the curved portion of the tubing the "connecting means" and to establish that the catheter and the connecting means are physically separate and distinct is a question of fact best resolved by the trier of fact. *See International Rectifier Corp. v. IXYS Corp.*, 361 F.3d 1363, 1369 (Fed. Cir. 2004) (quoting *Gart v. Logitech, Inc.*, 254 F.3d 1334, 1339 (Fed. Cir. 2001)) ("[b]ecause infringement is a question of fact, infringement is properly decided at summary judgment only 'when no reasonable jury could find that every limitation recited in the properly construed claim either is or is not found in the accused device'").

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[14] Plaintiff's Reply Memorandum in Support of Summary Judgment on Literal Infringement of the `561 Patent is cited as "Pl. `561 Reply, at __."

Indeed, as noted, the structural differences in the Flexxicon II led Defendants to decline to seek summary judgment in their initial motion. Both motions for summary judgment regarding literal infringement as to the Flexxicon II are therefore denied.[15] Defendants' motion for summary judgment of non-infringement for the Flexxicon II based on the doctrine of equivalents is also denied. *See Kemco Sales*, 208 F.3d at 1364 (infringement of a means-plus-function claim under the doctrine of equivalents differs from literal infringement of such a claim only in that the identical function is not required).

2. Equivalence

The parties also seek summary judgment on the issue of infringement of the '561 patent under a theory of equivalence. "Although an equivalence analysis under § 112, ¶ 6, and the doctrine of equivalents are not coextensive (for example, § 112, ¶ 6, requires identical, not equivalent function) and have different origins and purposes, their tests for equivalence are closely related." *Chiuminatta*, 145 F.3d at 1310. Specifically,

> [b]oth § 112, ¶ 6, and the doctrine of equivalents protect the substance of a patentee's right to exclude by preventing mere colorable differences or slight improvements from escaping infringement, the former, by incorporating equivalents of disclosed structures into the literal scope of a functional claim limitation, and the latter, by holding as infringements equivalents that are beyond the literal scope of the claim. They do so by applying similar analyses of insubstantiality of the differences. Thus, a finding of a lack of literal infringement for lack of equivalent

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[15] In a footnote, Defendants point out that Dr. Mahurkar failed to respond to a May 25, 1995 letter from attorneys representing the alleged manufacturer of the Flexxicon II (Vas-Cath, Inc.) in which they explained why the Flexxicon II did not infringe the '561 patent. Defendants argue that Dr. Mahurkar's silence in response to this letter "led Defendants to reasonably infer that Plaintiff did not intend to enforce his '561 patent, and Defendants, who relied on Plaintiff's conduct, would be materially prejudiced if Plaintiff was now allowed to recover damages on catheters produced during the period when Plaintiff knowingly chose to remain silent." (Def. '561 Resp., at 9 n.8.) This theory of equitable estoppel has not been developed and, thus, does not support summary judgment. *See, e.g., ICN Photonics, Ltd. v. Cynosure, Inc.*, 73 Fed.Appx. 425, 2003 WL 21675334, at *6 (Fed. Cir. July 16, 2003) (noting that the defendant "might ultimately prevail on this argument, but the record is not adequately developed to decide at this point"); *United States v. Berkowitz*, 927 F.2d 1376, 1384 (7th Cir. 1991) ("perfunctory and undeveloped arguments . . . are waived").

> structure under a means-plus-function limitation may preclude a finding of equivalence under the doctrine of equivalents.

Id.

"To establish infringement under the doctrine of equivalents, the accused device must be shown to include an equivalent for each literally absent claim limitation." *Dawn Equip. Co. v. Kentucky Farms Inc.*, 140 F.3d 1009, 1015 (Fed. Cir. 1998). An element in the accused product is equivalent to a claim element if the differences between the two are "insubstantial to one of ordinary skill in the art." *Boehringer Ingelheim Vetmedica, Inc. v. Schering-Plough Corp.*, 320 F.3d 1339, 1351 (Fed. Cir. 2003) (citing *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 40 (1997)). "[T]he insubstantial differences inquiry may be guided by determining whether the element in the accused device 'performs substantially the same function in substantially the same way to obtain the same result' as the claim limitation'" – i.e., the "function-way-result" test. *Id.* Similarly, two devices may be equivalent for purposes of § 112 ¶ 6 if "they perform the identical function, in substantially the same way, with substantially the same result." *Kemco Sales*, 208 F.3d at 1364.

Dr. Mahurkar claims that the Softcell Group catheters include a known equivalent of the "unitary connecting member" structure, again based on his theory that the connecting means in the Softcell Group is "fastened" to the catheter "where the straight catheter component meets with the curved connecting member." (Pl. `561 Resp., at 14; `561 Patent, col. 8, lines 16-19 ("the curved passageways provided by those extension tubes may instead be formed by a unitary connecting member fastened to the proximal end of the dual-lumen catheter").) While acknowledging that the patent language "does not explicitly teach that the catheter and the connecting member form an integral unitary structure," Dr. Mahurkar argues that "integral formation of two portions of a catheter assembly was a known equivalent to fastening 'separate' portions to each other at the time the `561 patent issued." (*Id.* at 14-15.) In support of this argument, Dr. Mahurkar refers the court to

U.S. Patent No. 4,583,968 (the "`968 patent"), issued to him on April 22, 1986 for a hemodialysis catheter consisting of a straight catheter tube connected to a Y-connector with two straight extension tubes. The `968 patent states that the "tip" of the catheter is "easily molded and bonded or is integrally formed from the cylindrical tube by the use of internal and external mandrels and the application of heat." (`968 Patent, Ex. H to Pl. `561 Facts, col. 4, lines 29-37.)

Defendants respond that construing the connecting means – i.e., the curved tubing – as "integrally" formed with the straight tubing "would vitiate two [claim] limitations: 'curved' and 'attached.'" (Def. `561 Reply, at 8.)[16] *See also Tronzo v. Biomet, Inc.*, 156 F.3d 1154, 1160 (Fed. Cir. 1998) ("[i]f a theory of equivalence would vitiate a claim limitation . . . then there can be no infringement under the doctrine of equivalents as a matter of law"). In Defendants' view, integral formation of the catheter and the unitary connecting member is inconsistent with the court's determination that the two elements must be "physically separate" and "visibly distinct" from each other in order to be "attached." The accused devices satisfy those attachment requirements, Defendants say, only at the point where the tubing meets the Y-connector and straight extension tubes. If the Y-connector with straight extension tubes constitutes the "connecting means," however, then there is no curved element as required by the patent language. (*Id.*)

In this court's view, there may be some tension between claim construction, which excludes certain structures not identified in the patent, and the doctrine of equivalents, which would appear to allow claims to proceed notwithstanding a claim construction. Case law on this issue has not fully illuminated the matter. In *Searfoss v. Pioneer Consol. Corp.*, 374 F.3d 1142 (Fed. Cir. 2004), for example, the court construed a patent for a moveable cover system for truck beds as requiring a direct connection between the "tension bail" and the "extension assembly." *Id.* at 11449-50. The accused products, which had an indirect connection, were not equivalent to the patented design

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[16] Defendants' Reply Memorandum in Support of Motion for Summary Judgment of Non-Infringement of the `561 Patent is cited as "Def. `561 Reply, at __."

because such a construction "would, in effect, completely vitiate the connection function." *Id.* at 1151. In *Ethicon Endo-Surgery, Inc. v. U.S. Surgical Corp.*, 149 F.3d 1309 (Fed. Cir. 1998), conversely, the patentee alleged infringement of its "lockout mechanism" for use in linear cutter staplers, used by surgeons. *Id.* at 1311. The patent claimed, among other things, a restraining structure that contacted a barrier "during the staple firing stroke." *Id.* at 1313. The accused product used a restraint that lost contact with the barrier just prior to the staple firing stroke and, thus, did not literally infringe the patent. *Id.* at 1315. The court found, however, a question of fact as to whether the accused product infringed the patent under the doctrine of equivalents. The court noted that only a few millimeters distinguished the length of the pusher bars, which are involved in expelling staples, in the patented product and the accused devices and held that there were genuine issues of fact as to whether this difference was substantial. *Id.* at 1320-21.

Here, the court concludes that a determination whether integral formation of the curved and straight portions of the catheter tubing in the accused products constitutes the equivalent of a "connecting means" that is "attached" to the catheter is a question of fact. *See Teleflex, Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1323 (Fed. Cir. 2002) (determination of infringement, both literal and under the doctrine of equivalents, is a question of fact). The function of the connecting means is "attaching the proximal end of the catheter to the portion of the assembly which forms a pair of internal passageways which communicate at one end thereof with the dual lumens in the catheter." *Mahurkar I*, 2003 WL 21078033, at *9. The accused products do not include literal equivalents of the relevant claim limitations because the straight portion of tubing is not physically separate and visibly distinct from the curved portion of tubing. Defendants' motion for summary judgment based on literal infringement by an equivalent structure is therefore granted, and Dr. Mahurkar's corresponding motion is denied.

Nevertheless, a reasonable jury could conclude that the curved tubing in the accused products performs a substantially similar function in substantially the same way as the claim

limitation. *See Dawn Equip.*, 140 F.3d at 1015. Significantly, the curved portion of tubing has two lumens that bend back towards the distal end of the catheter such that forces exerted on the curved tubing and the attached Y-connector and straight extension tubes arguably tends to move the catheter in the same direction as the exerted forces – just as described in the `561 patent.

Defendants object that Dr. Mahurkar is attempting to ignore claim limitations in the patent by arguing that the straight and curved portion of tubing is integrally formed to satisfy the attachment requirement. *See, e.g., Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1578 (Fed. Cir. 1996) ("the doctrine of equivalents is not a license to ignore or 'erase . . . structural and functional limitations of the claim'"). This is not necessarily the case. In *Wright Medical Technology, Inc. v. Osteonics Corp.*, 122 F.3d 1440 (Fed. Cir. 1997), for example, the plaintiff claimed that the defendant's knee surgery device infringed its patent relating to artificial knees because both devices contained intermedullary rods. *Id.* at 1441-42, 1445. The independent claim at issue defined a femoral surface shaping guide comprising "an intermedullary rod portion adapted to closely fit in and extend through the narrowest portion of the human femur." *Id.* at 1442. The district court construed "closely fit" to mean "a tight or snug fit between the rod and the isthmus of the femur," and construed "extend through" to require that the "rod pass through the entire length of the isthmus." *Id.* at 1444. Based on this construction, the parties agreed that the accused device did not literally infringe the plaintiff's patent because its intermedullary rods did not fit tightly against or extend through the isthmus of the femur. *Id.*

The parties disputed, however, whether the accused device infringed under the doctrine of equivalents. *Id.* at 1445. The district court granted summary judgment to the defendant, stating that the plaintiff's theory of infringement by equivalence "attempt[ed] to ignore claim limitations on which the public is entitled to rely." *Id.* The Federal Circuit reversed, holding that it was for a fact finder to determine whether the intermedullary rod in the accused product was the equivalent of the one in the claimed invention. *Id.* at 1446. *See also Novartis Pharmaceuticals Corp. v. Abbott*

Laboratories, 375 F.3d 1328, 1338-39 (Fed. Cir. 2004) (noting that in *Wright Medical*, "although the intermedullary rod in the accused product did not tightly fit and extend through the isthmus of the femur, as required by the literal claim language, the absence of those claimed limitations did not vitiate the fact that the accused product possessed an 'intermedullary rod'").

In this case, the accused products have a catheter and a connecting means which are "attached" to each other. Notwithstanding the court's claim construction, Dr. Mahurkar has raised a question of fact as to whether a unitary structure is an insubstantially different method of attaching those two elements together. Indeed, equivalency can exist "when separate claim limitations are combined in a single component of the accused device" – in this case, the "catheter" and the "connecting means." *Dolly, Inc. v. Spalding & Evenflo Companies, Inc.*, 16 F.3d 394, 398 (Fed. Cir. 1994); (Pl. '561 Resp., at 20.) Defendants again note that a court cannot "convert a multi-limitation claim to one of [fewer] limitations to support a finding of equivalency." *Dolly*, 16 F.3d at 399 (quoting *Perkin-Elmer Corp. v. Westinghouse Elec. Corp.*, 822 F.2d 1528, 1532 (Fed. Cir. 1987)). *See also Liquid Dynamics Corp. v. Vaughan Co.*, 355 F.3d 1361, 1369 (Fed. Cir. 2004) ("every claim limitation or its equivalent [must be] found in the accused device"). This argument, however, is premised on the notion that the catheter and the connecting means cannot be "attached" unless physically separate and visibly distinct. As noted, there is a question of fact as to whether integral formation satisfies the attachment limitation under an equivalence theory and, thus, summary judgment is not appropriate on this basis.

Dolly is not to the contrary. The parties in *Dolly* both manufactured a portable, adjustable child's chair. 16 F.3d at 396. The plaintiff's patent included a specific requirement that "the stable rigid frame must be formed independent of the seat and back panels." *Id.* at 397. The defendant's allegedly infringing chair formed a stable rigid frame using back, side, and seat panels, which the district court held was the equivalent of the limitation set forth in the patent. *Id.* The Federal Circuit

disagreed, finding that the accused chair could not be equivalent to the patented chair because it did not have a stable rigid frame apart from the back and seat panels as stated in the patent:

> A stable rigid frame assembled from the seat and back panels is not the equivalent of a separate stable rigid frame which the claim language specifically limits to structures exclusive of seat and back panels. The district court erred by failing to give effect to this claim limitation in applying the doctrine of equivalents to the [accused] chair.

Id. at 400. Unlike in *Dolly*, the `561 patent does not include the terms "physically separate" or "visibly distinct"; rather, it requires that the catheter and connecting means be "attached." Although the matter is not free from doubt, the court believes that it is for the trier of fact to decide whether integral formation satisfies the attachment requirement.

Defendants next argue that the doctrine of equivalents cannot apply here because the accused products use technology that pre-dates the `561 patent. Unlike § 112 ¶ 6, the doctrine of equivalents is necessary to account for technological advances that may be used to vary an element of a patented device in an insubstantial way. "Such a variant, based on after-developed technology, could not have been disclosed in the patent. Even if such an element is found not to be a § 112, ¶ 6 equivalent because it is not equivalent to the structure disclosed in the patent, this analysis should not foreclose it from being an equivalent under the doctrine of equivalents." *Chiuminatta*, 145 F.3d at 1310. At the same time, technology that pre-dates an invention could have been disclosed in the patent. "In such a case, a finding of non-equivalence for § 112, ¶ 6, purposes should preclude a contrary finding under the doctrine of equivalents." *Id.* at 1311.

Defendants claim that a bent shaft configuration for a dual lumen hemodialysis catheter was described in Canadian Patent No. 1,150,122 (the "Canadian `122 patent"), which discloses:

> a dual lumen cannula, having inner and outer lumens located co-axially so that only one insertion into the vein of the patient is required. Both of the lumens are elongated and the inner lumen is more flexible than the outer lumen which is pre-formed to have an accurate curve reflecting the general shape of the subclavian vein.

(Def. `561 Reply, at 12; Def. `561 Fact Reply ¶ 52; `122 Patent, Ex. 1 to Moore Decl., at BAS003338.)[17] The Canadian `122 patent, which Dr. Mahurkar produced to Defendants during discovery, issued on July 19, 1983, more than four years before the date on which Dr. Mahurkar filed for his `561 patent on May 16, 1988, and includes an illustration of the pre-curved catheter configuration. (*Id.*; `122 Patent, Ex. 1 to Moore Decl., at BAS 003351.) The curve, however, is described as "arcuate" or bow-shaped; is designed to "reflect[] the general shape of the subclavian vein"; and "is sufficiently flexible to be straightened during insertion without damage or kinking" – none of which can be said of the `561 patent or the accused products. (`122 Patent, Ex. 1 to Moore Decl., at BAS 003335, BAS 003338.) At the same time, the `122 catheter does not bend around to the distal end of the catheter as do the `561 patent and the accused products. Thus, the court is not satisfied that Defendants' catheters employ technology that pre-dates the `561 patent.

Defendants are correct that at least one of Dr. Mahurkar's arguments in opposition to summary judgment is unavailing. Specifically, a statement made by C.R. Bard's patent counsel, Kent Burningham, does not support a finding of infringement in this case. According to Dr. Mahurkar, Mr. Burningham told Defendants that the question of infringement of the `561 patent by a bent shaft catheter is a "very close thing." (Pl. `561 Resp., at 21.) Dr. Mahurkar's only evidence of this alleged statement, however, is an e-mail message drafted by someone named Len DeCant in which DeCant recounts a conversation he had with Mr. Burningham. (E-mail from DeCant to Jordan et al. of 7/1/97, Ex. E to Pl. `561 Fact Resp.) Aside from being inadmissible hearsay, Defendants insist that Mr. Burningham was opining on U.S. Patent No. 4,451,252, owned by Defendants, which was being challenged in the U.S. Patent and Trademark Office ("PTO") at the time. (Def. `561 Reply, at 13.)

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[17] Defendants' Reply to Plaintiff Mahurkar's Local Rule 56.1(b)(3)(B) Statement is cited as "Def. `561 Fact Reply ¶ __."

Nevertheless, for the reasons stated, Dr. Mahurkar has raised a question of fact as to whether the Softcell Group catheters infringe the `561 patent under the doctrine of equivalents and Defendants' motion for summary judgment on this issue is denied.

II. Plaintiff's Motion for Summary Judgment on Defendants' Licensee Affirmative Defense

Defendants have asserted several affirmative defenses to liability in this case, including a licensee affirmative defense which is premised on the theory that C.R. Bard acquired the licensing rights of Vas-Cath, Inc., a small Canadian catheter manufacturer, as to the Softcell, Optiflow, and Hemoglide catheters. Dr. Mahurkar claims that the licensee defense is "a sham devoid of any factual foundation or legal significance" and seeks partial summary judgment on that issue.

A. Background

1. Mahurkar/Vas-Cath Consent Judgment

The licensee defense arises from prior litigation in the Northern District of Illinois between Dr. Mahurkar and Vas-Cath (Case No. 90 C 5909) involving alleged infringement of several patents, including the `155 and `561 patents at issue in this case. On April 30, 1992, Dr. Mahurkar and Vas-Cath reached a settlement which was embodied in three separate agreements: (1) a Consent Judgment Order ("CJO"); (2) a Settlement Agreement; and (3) a License Agreement.[18] The CJO states that Vas-Cath "shall not hereafter infringe the Mahurkar Patents in any way, including . . . by making or selling in the United States any . . . semi-circular, double-D, dual-lumen catheters . . . [including] . . . FLEXXICON and FLEXXICON BLUE catheters (Exhibit B), SOFTCELL (straight) and SOFTCELL (precurved) (Exhibits C and D)." (CJO, Ex. B to Stolte Decl., ¶ 4.) The

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[18] Vas-Cath's distributors, Gambro, Inc. and Omni Medical Products, Inc., and Vas-Cath's principals, Geoffrey and M. Jane Martin, are also subject to the underlying litigation and CJO.

CJO further states that "[i]t is admitted that . . . Vas-Cath . . . ha[s] infringed the Mahurkar Patents . . ." (*Id.*) By signing the CJO, Dr. Mahurkar waived and discharged

> any and all existing and future claims they have or may have anywhere in the world against Vas-Cath, Gambro, Omni, their officers, directors, employees, agents, distributors, customers or end-users for infringement of any of the existing Mahurkar patents . . . with respect to catheters . . . of the following disclosed structures and designs: FLEXXICON II Coaxial catheter (Exhibit E); LACHHEIN Dual Lumen catheter (Exhibit F); SOFTCELL II (straight) (Exhibit G) and SOFTCELL II (precurved) (Exhibit H).

(*Id.* ¶ 8.) In exchange for this release, Vas-Cath agreed to, and did in fact pay Dr. Mahurkar and his then-licensee, Quinton Instruments Company, lump sum royalties totaling $1,800,000 spread over a number of years. (*Id.* ¶ 6; Def. Licensee Facts ¶ 4.)[19]

The Settlement Agreement set forth "the basis upon which this Settlement Agreement, the Consent Judgment Order and the License have been agreed to." (Settlement Agreement, Ex. C to Stolte Decl., ¶ 1.) The agreement specifically provided that "[t]he terms of the Consent Judgment Order shall be binding upon and enure to the benefit of the successors and assigns of the parties and each of them." (*Id.* ¶ 2.) The License Agreement, which related to a triple lumen Trialysis catheter not at issue in this case, stated that the agreement between the parties was

> personal and shall not be assigned by the Licensee to any other business or entity, nor shall it be extended to any third party that purchases any part of Licensee's assets or stock, without the prior written consent of Licensor, which consent shall not be withheld if the entirety of Licensee's dialysis business is sold to a third party.

(License Agreement, Ex. A to Moore Decl., § VI(B); Pl. Licensee Facts ¶ 10 n.2.)[20]

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[19] Defendants' Statement of Additional Facts in Response to Plaintiff's Local Rule 56.1 Statement of Undisputed Facts in Support of Plaintiff's Motion for Summary Judgment on Defendants' Licensee Affirmative Defense is cited as "Def. Licensee Facts ¶ __."

[20] The Local Rule 56.1 Statement of Undisputed Facts in Support of Plaintiff's Motion for Summary Judgment on Defendants' Licensee Affirmative Defense is cited as "Pl. Licensee Facts ¶ __."

2. Mahurkar/C.R. Bard License Agreement

Also in the early 1990s, Dr. Mahurkar sued C.R. Bard for patent infringement under the '155 patent, Case No. 92 C 4803. After a lengthy trial on the merits in August 1994, a jury found that a C.R. Bard product not at issue here infringed the '155 patent and that Bard had not proven invalidity. Judge Zagel awarded damages under a reasonable royalty rate of 25.88% of C.R. Bard's total net sales of the infringing catheter at issue, plus a nine percent "Panduit kicker."[21] (Pl. Licensee Facts ¶ 13; Def. Licensee Facts Resp. ¶ 13; Transcript of Trial Proceedings Before Judge Zagel dated 9/2/94, Ex. D to Pl. Licensee Facts, at 2473-74.) C.R. Bard appealed the issues of infringement, validity and damages to the Federal Circuit, which affirmed all findings except the damage "kicker," which it vacated. (*Id.* ¶ 14.) *See also Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572 (Fed. Cir. 1996). Following remand on the damage "kicker" issue, the parties signed an Agreed Order and entered into a License Agreement in June 1996. (Pl. Licensee Facts ¶ 15; Def. Licensee Fact Resp. ¶ 15; Pl. Licensee Fact[22] Reply ¶ 15.)

Under the June 1996 License Agreement, C.R. Bard must pay Dr. Mahurkar a royalty of "25.88% of the Net Sales Price of Licensed Products." (License Agreement, Ex. E to Stolte Decl., at 2-3.) "Licensed Products" means "any catheter covered by any claim in the Licensed Patent Rights and shall include all kits, trays or other components or products sold or packaged with any catheter covered by any claim in the Licensed Patent Rights." (*Id.* at 1.) "Licensed Patent Rights"

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[21] Judge Zagel was referring to *Panduit Corp. v. Stahlin Bros. Fibre Works, Inc.*, 575 F.2d 1152 (6th Cir. 1978), in which the Sixth Circuit held that a patentee could recover damages by proving: (1) a demand for the patented product; (2) the absence of acceptable, noninfringing substitutes; (3) the patentee's capacity to exploit the demand; and (4) the profits lost due to infringement. *Id.* at 1156.

[22] Defendants' Response to Plaintiff's Local Rule 56.1 Statement of Undisputed Facts in Support of Plaintiff's Motion for Summary Judgment on Defendants' Licensee Affirmative Defense is cited as "Def. Licensee Fact Resp. ¶ __." Plaintiff's Reply to Defendants' Response to Plaintiff's Local Rule 56.1 Statement of Undisputed Facts in Support of Plaintiff's Motion for Summary Judgment on Defendants' Licensee Affirmative Defense is cited as "Pl. Licensee Fact Reply ¶ __."

are defined as the '155 patent and "any divisions, continuations, continuations-in-part or reissues thereof." (*Id.*) "Net Sales Price" means "(1) the amount invoiced to Licensee's customers who are end users f.o.b. Licensee's factory, exclusive of allowances for returns, duties or taxes, or (2) if sold through distributors, then the amount invoiced by such distributors to end users." (*Id.* at 1-2.) The license was granted to C.R. Bard and "its wholly-owned subsidiaries," and was "personal, non-exclusive and non-transferable." (*Id.* at 2.)

3. Bard Canada Acquires Vas-Cath

During the course of the Mahurkar/C.R. Bard litigation, C.R. Bard became aware of the 1992 CJO between Dr. Mahurkar and Vas-Cath. (Pl. Licensee Facts ¶ 18.) Within weeks of the August 1994 jury verdict, C.R. Bard initiated negotiations with Vas-Cath concerning acquisition of Vas-Cath and its catheter business, valued at that time at $15 million in annual sales. (*Id.* ¶ 19.) In a letter dated September 22, 1994 from C.R. Bard's U.S. counsel to Vas-Cath's Canadian counsel, C.R. Bard stated:

> One of the issues in the negotiations between our clients is that [sic] the status of Vas-Cath's right to manufacture the SoftCell II catheter, both straight and precurved, without liability for infringement of patents issued to Sakharam D. Mahurkar. Another issue is whether Vas-Cath can transfer such rights, if any, to any purchaser of the stock assets of Vas-Cath.

(*Id.* ¶ 20; Letter from Workman to Jolliffe of 9/22/94, Ex. F to Moore Decl.)

On December 2, 1994, Bard Canada, Inc., a subsidiary of C.R. Bard, purchased all outstanding stock of Vas-Cath. (*Id.* ¶ 21; Interrogatory Responses, Ex. H to Pl. Licensee Facts, at 5; Def. Licensee Facts ¶ 9.) Vas-Cath remained a duly-chartered Canadian corporation and became a wholly-owned subsidiary of Bard Canada. (Def. Licensee Facts ¶ 10; Ex. H to Pl. Licensee Facts, at 6.) Vas-Cath notified Dr. Mahurkar of the acquisition by letter dated December 16, 1994. (*Id.* ¶ 11; Letter from M. Martin to S. Mahurkar of 12/16/94, Ex. C to Moore Decl.) Dr. Mahurkar responded with a letter dated January 13, 1995 in which he purported to cancel the

License Agreement. (*Id.* ¶ 12; Letter from S. Mahurkar to M. Martin of 1/13/95, Ex. D to Moore Decl.) On February 17, 1995, Ms. Martin sent Dr. Mahurkar another letter denying any wrongful transfer or assignment of rights under the 1992 License Agreement. (Letter from M. Martin to S. Mahurkar of 2/17/95, Ex. J to Pl. Licensee Facts.)

In late 1994 or early 1995, Bard Access Systems, a wholly-owned subsidiary of C.R. Bard, began selling the accused Softcell and Flexxicon II catheters in the United States. (Pl. Licensee Facts ¶ 22; Second Supp. Interrogatory Responses, Ex. I to Pl. Licensee Facts, at 4.) From the time of the acquisition until sometime in 1998 or 1999, Vas-Cath manufactured these catheters at its facility in Canada and sold them exclusively to Bard Access Systems for distribution in the United States. (*Id.* ¶ 23.) Bard Access Systems subsequently launched four additional catheters for U.S. distribution: the Niagara catheter in 1997, the Optiflow in 1998, the Niagara Slim-Cath in 2001, and the Hemoglide in 2002.[23] (*Id.* ¶ 24.)

4. Bard Reynosa Begins Manufacturing the Accused Catheters

In mid-1997, C.R. Bard developed a proposal "for the relocation of production development and marketing of certain PTA[24] products from the Vas-Cath location in Canada to Ireland or Mexico." (Letter from J. McAlonan to W. Egan of 5/28/97, Ex. K to Pl. Licensee Facts.) An internal memo dated May 13, 1997 indicated that the relocation would include moving Vas-Cath research and development to Salt Lake City, Utah, and that the overall proposal "would make VasCath in Canada a virtual organization." (Ex. K, Bates No. ACB 01433.) C.R. Bard ultimately chose Reynosa, Mexico as the site for the manufacture of the Vas-Cath line of catheter products, and on January 12, 1998, Bard Reynosa was incorporated in Mexico as a wholly-owned subsidiary of Vas-Cath. (Pl. Licensee Facts ¶ 28.) In the months that followed, C.R. Bard, Bard Access Systems,

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[23] The parties do not specify whether these additional catheters were also manufactured by Vas-Cath and sold to Bard Access Systems.

[24] The proposal does not define the term "PTA."

Vas-Cath and Bard Reynosa made detailed arrangements and plans for the transfer of manufacturing responsibility for the accused catheters to Bard Reynosa. (*Id.* ¶ 29.)

On September 24, 1998, C.R. Bard entered into a "Maquila Agreement" with Bard Reynosa,[25] which stated that Bard Reynosa would provide manufacturing services on behalf of C.R. Bard and that C.R. Bard would in turn deliver all raw materials, components, subassemblies, supplies, machinery, equipment and know-how necessary to allow Bard Reynosa to manufacture the relevant products. (*Id.* ¶¶ 30, 31.) Defendants deny that the Maquila Agreement covers the accused catheters, noting that it does not mention them "at all." (Def. Licensee Fact Resp. ¶¶ 30, 31.) Defendants' Rule 30(b)(6) witness, Bard Healthcare Plant Comptroller Todd Garner, testified, however, that the Maquila Agreement related to "everything Bard Reynosa does" which, in Dr. Mahurkar's view, "would necessarily include the accused catheters." (Garner Dep., at 6, 71-72; Pl. Licensee Fact Reply ¶¶ 30, 31.)

On January 6, 2000, C.R. Bard and Bard Reynosa executed an Addendum to the Maquila Agreement giving C.R. Bard a right to assign all or part of its obligations under the agreement to "any entity controlling, controlled by or under common control" with C.R. Bard. (Pl. Licensee Facts ¶ 35.) Defendants admit that C.R. Bard never made a written assignment under this Addendum but claim that "Vas-Cath has received an oral assignment under the 'Maquila Agreement.'" (Def. Licensee Fact Resp. ¶ 36.) Dr. Mahurkar responds that Defendants "have never been able to supply any details, such as the time, place, salient terms, or the identities of the persons by which this phantom oral assignment may have been conveyed." (Pl. Licensee Fact Reply ¶ 36.)

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[25] Vas-Cath is not a party to the Maquila Agreement nor mentioned in it. (Pl. Licensee Facts ¶ 34.) The parties have not explained the origin of this title, but the court understands it is used generally to describe "any partial activity in a manufacturing process, such as assembly or packaging carried out by someone other than the original manufacturer." *See* http://www.maquilaportal.com/Visitors_Site/nav21.htm

By late 1998 or early 1999, Vas-Cath ceased all direct manufacturing of the accused catheters in Canada, and Bard Reynosa took over production of the products at its plant in Mexico. Since at least early 1999, Bard Reynosa has manufactured all of the accused catheters except the Niagara SlimCath, which is manufactured by a non-Bard-related company, Medron, Inc. (Pl. Licensee Facts ¶¶ 39, 40.) Vas-Cath has no office in the United States or Canada and, according to Dr. Mahurkar, no manufacturing facility or employees. (*Id.* ¶ 41; Garner Dep., at 24, 42-44.) Todd Garner testified that (1) he signs the checks to pay for all raw materials; (2) Bard Healthcare's Plant Manager, John Warburton, manages the Bard Reynosa operations on behalf of C.R. Bard; (3) Bard Healthcare's Information Systems Manager, Rudy Valdez, receives product orders "on Vas-Cath's books" from Bard Access Systems and orders the raw materials from which the catheters are manufactured; (4) Bard Healthcare and Bard Reynosa employees process the invoices for the raw materials; and (5) Bard Healthcare imports the accused catheters from Mexico to the United States and pays the importing fees. (Garner Dep., at 16, 22-23, 28-29, 43-46, 48, 53-56.)

Vas-Cath's involvement in the manufacturing process thus appears to be one of form rather than substance. Defendants nevertheless claim that Vas-Cath continues to manufacture catheters "through its wholly-owned subsidiary, Bard Reynosa," and that "Vas-Cath owns a manufacturing facility by virtue of its ownership of Bard Reynosa, Vas-Cath's wholly-owned subsidiary." (Def. Licensee Fact Resp. ¶¶ 39-41.) Citing their unverified interrogatory responses, Defendants admit that Bard Healthcare imports the accused catheters into the United States for delivery to Bard Access Systems, but insist that this occurs "after the catheters have been purchased from Vas-Cath." (*Id.* ¶ 43.) In Defendants' view, Vas-Cath purchases the raw materials, which are then delivered to Bard Reynosa for manufacture. Vas-Cath "maintains title to the raw materials and unfinished catheters at all times, and ownership of the accused catheters is transferred directly from Vas-Cath to Bard Access Systems when the finished catheters leave the loading dock in

Reynosa, Mexico." (*Id.*) Defendants admit that Bard Healthcare "maintains Vas-Cath's bookkeeping and provides all financial information concerning the manufacture and sale of the accused catheters to C.R. Bard's treasury department so that C.R. Bard can periodically infuse cash into Vas-Cath's Canadian bank account and make the necessary intercompany transfers relating to the accused catheters." (Pl. Licensee Facts ¶ 44; Def. Licensee Fact Resp. ¶ 44.)

B. Analysis

In their affirmative defense, Defendants claim that the accused Softcell, Optiflow and Hemoglide catheters are licensed (or at least released from any liability for infringement) by virtue of the 1992 CJO between Dr. Mahurkar and Vas-Cath; specifically, Defendants purportedly purchase the catheters from Vas-Cath, which is a licensee of Dr. Mahurkar. (Def. Licensee Fact Resp. ¶ 42.) The parties agree that the Settlement Agreement and CJO granted Vas-Cath a nonexclusive license under the `155 and `561 patents. (Pl. Licensee Mem., at 12; Def. Licensee Resp., at 5.)[26] They disagree, however, as to whether Vas-Cath assigned its license rights to the Bard defendants and, if so, whether it was effective.

Dr. Mahurkar argues that C.R. Bard "essentially assigned, indirectly, Vas-Cath's [license] rights to Bard Reynosa, Bard Access Systems, Bard Healthcare and even to a non-Bard entity, Medron, Inc." (Pl. Licensee Mem., at 15.) His theory is as follows. Bard Canada bought Vas-Cath on December 2, 1994, shortly after a jury found C.R. Bard liable for infringing Dr. Mahurkar's `155 patent in Case No. 92 C 4803. C.R. Bard knew from that litigation that Vas-Cath had license rights in the `155 and `561 patents through the CJO and Settlement Agreement. For the next several years until late 1998 or early 1999, Vas-Cath manufactured the Softcell and Flexxicon II catheters at its facility in Canada and sold them exclusively to Bard Access Systems for distribution in the

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[26] The Memorandum in Support of Plaintiff's Motion for Summary Judgment on Defendants' Licensee Affirmative Defense is cited as "Pl. Licensee Mem., at __." Defendants' Memorandum in Opposition to Plaintiff's Motion for Summary Judgment on Defendants' Licensee Affirmative Defense is cited as "Def. Licensee Resp., at __."

United States. Bard Access Systems subsequently began selling four additional catheters in the U.S.: the Niagara catheter in 1997, the Optiflow in 1998, the Niagara Slim-Cath in 2001, and the Hemoglide in 2002, though it is not clear whether Vas-Cath similarly manufactured those products for purchase by Bard Access Systems.

In any event, in mid-1997, C.R. Bard decided to relocate the production of catheters from Vas-Cath's facility in Canada to Reynosa, Mexico. After incorporating Bard Reynosa as a wholly-owned subsidiary of Vas-Cath, C.R. Bard and Bard Reynosa entered into the Maquila Agreement requiring C.R. Bard to supply all necessary raw materials, machines, equipment, and technical know-how necessary for Bard Reynosa to produce the accused catheters. By late 1998 or early 1999, Vas-Cath was no longer directly manufacturing any products and had no offices or employees. According to Defendants' 30(b)(6) witness, Todd Garner, Bard Healthcare and its employees managed the Bard Reynosa operations on behalf of C.R. Bard; received product orders "on Vas-Cath's books" from Bard Access Systems; ordered the raw materials from which the catheters are manufactured; processed the invoices for the raw materials; signed checks to pay for the raw materials; and imported the accused catheters from Mexico to the United States and paid the importing fees. (Garner Dep., at 16, 22-23, 28-29, 43-46, 48, 53-56.) Dr. Mahurkar characterizes Vas-Cath as a "virtual corporation" that exists in name only so that Defendants can use the company's license rights to manufacture otherwise infringing products. (Pl. Licensee Mem., at 15-17.)

Defendants claim that they are explicitly covered by the CJO, assignment or no assignment, because they are Vas-Cath's "customers"; that is, Vas-Cath "manufactures" the accused catheters because it owns Bard Reynosa. (*See* CJO, Ex. B to Stolte Decl., ¶¶ 7, 8) (waiving and discharging all claims against Vas-Cath and its customers). According to Defendants, Vas-Cath "maintains title to the raw materials and unfinished catheters at all times, and ownership of the accused catheters is transferred directly from Vas-Cath to Bard Access Systems when the finished catheters leave

the loading dock in Reynosa, Mexico." (Def. Licensee Fact Resp. ¶ 43.) All of this appears to happen on paper only, as Vas-Cath has no employees and no offices; indeed, Bard Healthcare employees themselves receive orders for Bard's ostensible vendor, record them "on Vas-Cath's books," and do all the work necessary to get the finished products to the United States. (Garner Dep., at 44-46.)

The court does not believe that Defendants have a colorable argument that they are covered by the CJO as "customers" of Vas-Cath that purchase finished catheters for sale in the United States. Vas-Cath is a distinct corporate entity under the laws of Canada, but it does not have any offices in the United States or Canada, nor any employees who receive orders from Bard Access Systems or manage the orders once placed. Instead, the orders somehow appear "on Vas-Cath's books," and then Bard Healthcare, which is not a subsidiary of Vas-Cath or Bard Reynosa, manages and processes those orders. On these facts, it can hardly be said that Vas-Cath and C.R. Bard have merely a customer-merchant relationship.

Nor is Vas-Cath acting as a "foundry" to produce products for distribution by Defendants. Defendants' theory is based on *Intel Corp. v. ULSI System Technology, Inc.*, 995 F.2d 1566 (Fed. Cir. 1993), in which Intel and Hewlett-Packard ("HP") entered into a cross-licensing agreement that allowed each to utilize the other's patents. *Id.* at 1567. Defendant ULSI contracted with HP to have HP act as its "foundry" and manufacture computer chips using Intel's patented technology, which ULSI then resold as ULSI products. *Id.* Intel sued ULSI for infringement and the district court granted its request for preliminary injunctive relief. *Id.* at 1567-68. The Federal Circuit reversed, finding that Intel's rights with respect to the products ended when HP sold the computer chips to ULSI. The "first sale" doctrine states that a purchaser of a patented product may use or resell the product free of the patent. *Id.* at 1568. The rule applies equally to a sale of a patented product manufactured by a licensee acting within the scope of its license. *Id.* The court found that "HP's

conceded right to sell the chips deprives Intel of any claim of infringement, as long as HP sold the chips," which it did to ULSI. *Id.* at 1569.

Unlike in *Intel*, Vas-Cath does not actually manufacture the products which it allegedly sold to Defendants; that is done by non-license holders Bard Reynosa and Medron, Inc. Defendants disagree, explaining that Vas-Cath manufactures products through its wholly-owned subsidiary, Bard Reynosa. (Def. Licensee Fact Resp. ¶¶ 39-41.) This argument is undermined by the fact that it was C.R. Bard and not Vas-Cath that entered into the "Maquila Agreement" with Bard Reynosa. That agreement stated that Bard Reynosa would provide manufacturing services on behalf of C.R. Bard and that C.R. Bard would provide all raw materials, components, subassemblies, supplies, machinery, equipment and know-how necessary to allow Bard Reynosa to manufacture the relevant products. (Pl. Licensee Facts ¶¶ 30, 31.) Defendants deny that the Maquila Agreement covers the accused catheters, but their Rule 30(b)(6) witness, Todd Garner, testified that the Maquila Agreement related to "everything Bard Reynosa does," which would include the manufacture of the accused catheters. (Garner Dep., at 6, 71-72.) Defendants claim that "Vas-Cath has received an oral assignment under the 'Maquila Agreement'" pursuant to a January 2000 Addendum giving C.R. Bard a right to assign all or part of its obligations under the agreement to "any entity controlling, controlled by or under common control" with C.R. Bard. (Pl. Licensee Facts ¶ 35; Def. Licensee Fact Resp. ¶ 36.) Defendants have not, however, supplied any details regarding the time, place, terms, or parties involved in the alleged assignment. (Pl. Licensee Fact Reply ¶ 36.) On these facts, it appears that Bard Reynosa was manufacturing products on behalf of C.R. Bard, not Vas-Cath.

Even assuming that Vas-Cath was manufacturing the accused catheters through its subsidiary Bard Reynosa, it is well-established that a nonexclusive patent license is "personal to the licensee and not assignable unless expressly made so in the agreement." *Unarco Indus., Inc. v. Kelley Co.*, 465 F.2d 1303, 1306 (7th Cir. 1972). *See also Verson Corp. v. Verson Int'l*

Group PLC, 899 F. Supp. 358, 363 (N.D. Ill. 1995) ("[u]nder well-established law the holder of a nonexclusive patent license may not assign the license unless the right to assign is expressly provided for in the license agreement"). Moreover, there is no evidence that Vas-Cath assigned its licensing rights to Bard Reynosa, nor does the CJO purport to grant any license rights to Vas-Cath's subsidiaries.

Defendants argue that Vas-Cath did in fact have a right to assign the license to Bard because the Settlement Agreement between Dr. Mahurkar and Vas-Cath states that "the terms of the Consent Judgment Order shall be binding upon and enure to the benefit of the successors and assigns of the parties and each of them." (Settlement Agreement, Ex. C to Stolte Decl., ¶ 2.) The CJO itself says nothing about Vas-Cath's ability to assign its license rights to a third party, but Defendants argue that the parties intended to allow for assignment of the license as evidenced by the fact that they did not include language disallowing such assignment. In support of this position, Defendants direct the court to the License Agreement, executed the same day as the CJO, which does contain an explicit prohibition against assignment: the Agreement provides that the rights are "personal and shall not be assigned by the Licensee to any other business entity, nor shall it be extended to any third party that purchases any part of Licensee's assets or stock . . ." (Def. Licensee Resp., at 7.)

The court declines to imply a right to assign based on language in the Settlement Agreement, which is not incorporated by reference into the CJO and which does not expressly grant Vas-Cath any assignment rights or even state that the releases apply to Vas-Cath's assigns. *See, e.g., Stenograph Corp. v. Fulkerson*, 972 F.2d 726, 729 n.2 (7th Cir. 1992) (finding "dubious" an argument that license was assignable based on language in a settlement agreement that the terms of the agreement "shall extend to and be binding on all heirs, successors and assigns" of the parties; neither the agreement nor the license itself expressly specified that the license was assignable). The mere fact that the parties expressly disallowed assignment in a separate,

unincorporated License Agreement does not alone evidence an intent to allow assignment in the CJO. *See Verson*, 899 F. Supp. at 363 (requiring "compelling evidence of the parties' intent before implying a right to assign").

Defendants argue, however, that they are entitled to operate under the Settlement Agreement and CJO as Vas-Cath's successors. As noted, Dr. Mahurkar believes that Vas-Cath is operating as a "virtual corporation" and exists in name only to "give false legitimacy to Bard's licensee defense." (Pl. Licensee Mem., at 17.) Assuming Vas-Cath has ceased operations, Defendants argue, they are now Vas-Cath's successors. (Def. Licensee Resp., at 8) (citing *Toepper v. Brookwood Country Club Rd. Ass'n*, 204 Ill. App. 3d 479, 486, 561 N.E.2d 1281, 1285-86 (2d Dist. 1990)) (right to exercise seller corporation's rights "only accrue[s] where there has been a consolidation or merger of the corporation or the purchasing corporation is merely a continuation of the seller"). Defendants have not presented any facts demonstrating that Vas-Cath somehow merged with any of the Bard defendants, or that the entities were consolidated in any way. Indeed, Defendants repeatedly insist that Vas-Cath is a separate corporation that continues to this day. (Def. Licensee Fact Resp. ¶ 10; Def. Licensee Resp., at 5-6.) Thus, the court is not persuaded that Defendants are successors of Vas-Cath.

Defendants have not submitted any competent evidence to refute Dr. Mahurkar's contention that Defendants are using Vas-Cath as a pass-through corporation because Vas-Cath cannot assign its license rights directly to Defendants. *See, e.g., Cook Inc. v. Boston Scientific Corp.*, 333 F.3d 737, 743 (7th Cir. 2003) (where licensee bought medical stents from a third-party (ACS), added a patented coating to them and then sold them back to ACS for resale to hospitals and other users, "it [wa]s merely a device for defeating the anti-assignment clause" of the license agreement). Thus, Dr. Mahurkar's motion for partial summary judgment on Defendants' licensee affirmative defense is granted.

III. Plaintiff's Motion for Summary Judgment on Defendants' Invalidity Defense to the `155 Patent

Dr. Mahurkar next seeks summary judgment on Defendants' invalidity defense to the `155 patent. Relying on Judge Zagel's opinion in his 1992 lawsuit against C.R. Bard, Case No. 92 C 4803, Dr. Mahurkar claims that Defendants are collaterally estopped from arguing that U.S. Patent No. 4,403,984 filed by Stephen R. Ash and Marvin P. Loeb on December 22, 1980 (the "`984 Ash patent"), either alone or in conjunction with Dr. Mahurkar's U.S. Patent No. 4,134,402 (the "402 patent"), initially filed on February 11, 1976, or with U.S. Patent No. 4,385,631 filed by Ulrich Uthmann on March 18, 1981 (the "`631 Uthmann patent"), is prior art such that the `155 patent is invalid on obviousness grounds. Defendants dispute the import of Judge Zagel's opinion and argue that issues of fact preclude summary judgment.

A. Background

Dr. Mahurkar filed Case No. 92 C 4803 against C.R. Bard in July 1992, charging infringement of his `155 patent. (Pl. Validity Facts ¶ 1.)[27] C.R. Bard and Bard Access Systems filed a counterclaim seeking judgment that the `155 patent was invalid under 35 U.S.C. §§ 102, 103, and 112. (*Id.* ¶ 2.) The case proceeded to trial, during which the Bard defendants asserted that the `155 patent was invalid under § 102 of the Patent Act because it was anticipated by a July 1983 Cook, Inc. catalog disclosing a Cook Double Lumen Subclavian Hemodialysis Catheter. (*Id.* ¶ 3.) *See also Mahurkar v. C.R. Bard, Inc.*, 79 F.3d 1572, 1576 (Fed. Cir. 1996). Dr. Mahurkar testified at trial that he conceived and began work on dual-lumen, flexible catheters in 1979, and that from late 1980 through early 1981, he constructed polyethylene prototype catheters in his kitchen. As corroboration for this testimony, Dr. Mahurkar established that in 1981, he

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[27] The Local Rule 56.1 Statement of Undisputed Facts in Support of Plaintiff's Second Motion for Partial Summary Judgment on Validity of Plaintiff's `155 Patent is cited as "Pl. Validity Facts ¶ __."

confidentially disclosed the catheter prototype tips of his `155 invention to Geoffrey Martin, President of Vas-Cath, and to Brian L. Bates of Cook, Inc. *Mahurkar*, 79 F.3d at 1578. Dr. Mahurkar also produced an April 21, 1981 letter from Stephen Brushey, a Vas-Cath employee, that described several of his catheters, and an October 23, 1981 letter from Bates stating that he was impressed with Dr. Mahurkar's prototype material. *Id.* at 1578-79.

At the close of the evidence, the district court granted Dr. Mahurkar's motion for judgment as a matter of law ("JMOL"), finding that no reasonable jury could conclude the Cook catalog anticipated claim 1 of the `155 patent. *Mahurkar*, 79 F.3d at 1576. Dr. Mahurkar argued a conception date of 1979 and believes that Judge Zagel accepted that position. Defendants argue that Judge Zagel held only that the July 1983 Cook catalog was not prior art; he did not specifically find that Dr. Mahurkar conceived of the `155 patent in 1979 or on any specific date. (Pl. Validity Facts ¶¶ 6, 7; Def. Validity Fact Resp. ¶¶ 6, 7; Ex. D to Pl. Validity Facts, at 2041-59.)[28]

The issues of patent infringement and invalidity on obviousness grounds went to the jury, which found in August 1994 that C.R. Bard had infringed the `155 patent literally and under the doctrine of equivalents, and that C.R. Bard had not proved invalidity on obviousness grounds. (Pl. Validity Facts ¶ 8.) On October 24, 1994, Judge Zagel entered final judgment on the jury's verdict. C.R. Bard had filed a Motion for a New Trial on Invalidity under 35 U.S.C. §§ 102(a) and 112/102(b) based in large part on the theory that the Cook catalog was prior art to the invention claimed in the `155 patent, but Judge Zagel denied that motion on January 13, 1995. (*Id.* ¶ 9.) On appeal, the Federal Circuit affirmed the judgment of infringement and validity but remanded the case on the issue of damages. (*Id.* ¶ 10.) The court noted Dr. Mahurkar's testimony that he conceived the `155 catheter in 1979, corroborated by evidence from 1981. *Mahurkar*, 79 F.3d at 1578-79. The court

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[28] Defendants' Response to Plaintiff's Local Rule 56.1 Statement of Undisputed Facts re Plaintiff's Second Motion for Partial Summary Judgment on Validity of Plaintiff's `155 Patent is cited as "Def. Validity Fact Resp. ¶ __."

then stated generally that "[f]rom conception to filing, Dr. Mahurkar continuously sought to locate companies capable of extruding his tubing with the soft, flexible materials necessary for human use." *Id.* at 1579. After the Federal Circuit issued its ruling, the parties ultimately entered into a nonexclusive license agreement in June 1996. (Pl. Validity Facts ¶ 12.)

B. Analysis

Dr. Mahukar filed this lawsuit against C.R. Bard in November 2001 alleging infringement of the `155 and `561 patents. As one of its defenses, C.R. Bard claims that the invention of the `155 patent would have been obvious based on the following prior art: (1) the `984 Ash patent, filed with the PTO on December 22, 1980 and granted to Stephen R. Ash on September 13, 1983[29]; or, alternatively (2) the `984 Ash patent in view of Dr. Mahurkar's `402 patent; or, alternatively (3) the `984 Ash patent in view of the `631 Uthmann patent, filed with the PTO on March 18, 1981 and granted to Ulrich Uthmann on May 31, 1983. (Pl. Validity Facts ¶ 16; Def. Validity Facts ¶¶ 1, 2.) Under all of Defendants' invalidity theories, the `984 Ash patent is either the only reference relied upon or the primary reference to be combined with the other two secondary patent references. (*Id.*)

Whether a publication constitutes prior art is a question of law based on underlying fact questions. *TypeRight Keyboard Corp. v. Microsoft Corp.*, 374 F.3d 1151, 1157 (Fed. Cir. 2004). Section 102(e) of the Patent Act states that "a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent" may be regarded as prior art. 35 U.S.C. § 102(e); *Riverwood Int'l Corp. v. R.A. Jones & Co.*, 324 F.3d 1346, 1355 (Fed. Cir. 2003). It is generally recognized that the date of invention is the date of conception and not the date of reduction to practice. *See Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 60 (1998)

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[29] C.R. Bard claims that the `984 Ash patent is "a continuation-in-part" of an earlier application filed with the PTO on December 28, 1979. The PTO has informed Defendants' counsel that the 1979 filing for this patent is lost and the PTO is trying to locate it. (Defendants' Statement of Additional Facts re Plaintiff's Second Motion for Partial Summary Judgment on Validity of Plaintiff's `155 Patent ("Def. Validity Facts") ¶ 1.)

("[t]he primary meaning of the word 'invention' in the Patent Act unquestionably refers to the inventor's conception rather than to a physical embodiment of that idea").

Dr. Mahurkar argues that Judge Zagel and the Federal Circuit both recognized that he conceived of the '155 patent in 1979, before the '984 Ash patent and '631 Uthmann patent were filed with the PTO. In his view, this precludes any argument that the '984 Ash patent and the '631 Uthmann patent are prior art. Defendants claim that Judge Zagel merely concluded that Dr. Mahurkar had succeeded in pre-dating the July 1983 Cook catalog at issue in that case; he was not asked to establish a specific conception date and did not do so.

In affirming Judge Zagel's determination that the '155 patent pre-dated the Cook catalog, the Federal Circuit found that Dr. Mahurkar had reduced the invention of the '155 patent to practice as early as 1981. *Mahurkar*, 79 F.3d at 1578-79. The court noted Dr. Mahurkar's testimony at trial that he conceived and began work on dual-lumen, flexible catheters in 1979, and explained that "where a party seeks to show conception through the oral testimony of an inventor," there must be corroboration to address the concern that "inventors testifying in patent infringement cases would be tempted to remember facts favorable to their case by the lure of protecting their patent or defeating another's patent." *Id.* at 1577, 1578. The only corroborating evidence cited in that case was from 1981. Specifically, Geoffrey Martin, President of Vas-Cath, testified that he received prototype tips from Dr. Mahurkar in 1981. In addition, Dr. Mahurkar produced an April 21, 1981 letter from Vas-Cath employee Stephen Brushey that described several of Dr. Mahurkar's catheters, and an October 23, 1981 letter from Brian L. Bates of Cook, Inc. stating that he was impressed with Dr. Mahurkar's prototype material. *Id.* at 1578-79. This evidence was certainly sufficient to establish that the '155 patent was reduced to practice by 1981 and, thus, pre-dated the 1983 Cook catalog, which is what the Federal Circuit concluded. *Id.* at 1578 ("[v]iewing the evidence of record below in the light most favorable to Bard, this court concludes that no

reasonable jury could have found clear and convincing evidence that the Cook catalog was prior art").

The evidence from 1981 does not, however, conclusively establish that Dr. Mahurkar conceived of the `155 patent in 1979. The court did note generally that "Dr. Mahurkar . . . showed reasonable diligence from his conception date through the filing of his patent application [on October 24, 1983]. From conception to filing, Dr. Mahurkar continuously sought to locate companies capable of extruding his tubing with the soft, flexible materials necessary for human use." *Mahurkar*, 79 F.3d at 1579. In this court's view, however, this comment does not prove that Dr. Mahurkar necessarily conceived the `155 patent in 1979. After noting Dr. Mahurkar's testimony that he conceived of the `155 patent in 1979, the Federal Circuit stated that "[f]rom late 1980 through early 1981, Dr. Mahurkar constructed polyethylene prototype catheters in his kitchen," and that he tried to market his invention to Vas-Cath and Cook, Inc. in 1981. *Id.* at 1578-79. There is no indication what, if anything, Dr. Mahurkar did between 1979 and late 1980, nor does Dr. Mahurkar provide any evidence to corroborate his testimony that conception occurred in 1979 as opposed to some time in 1980 or 1981. Significantly, the court in that case was not considering prior art dating from late 1980 or early 1981, but from July 1983 – well after Dr. Mahurkar had received the April and October 1981 letters from Vas-Cath and Cook evidencing reduction to practice of his prototype tips.

Dr. Mahurkar claims that Judge Zagel expressly acknowledged that he "had proven at trial a conception date of 1979 and diligence toward reducing the `155 patented invention to practice," citing the following statement at the August 25, 1994 hearing on his motion for JMOL:

> THE COURT: Well, your position, Mr. Workman, would be I think that Mahurkar tells a story about conception in '79 and some form of device in '81 and that a jury could disbelieve this.

(Ex. D to Pl. Validity Facts, at 2042; Pl. Validity Reply, at 4.)[30] Judge Zagel's brief summary of the parties' theories in no way establishes that, by granting Dr. Mahurkar's motion for JMOL, the court accepted a conception date of 1979. To the contrary, as explained above, Judge Zagel merely determined that the 1983 Cook catalog was not prior art. (*Id.* at 2059.)

On these facts, the court finds that Dr. Mahurkar has not met his burden of proving all necessary elements to invoke collateral estoppel. These include:

> (1) the issue at stake must be identical to the one involved in the prior litigation; (2) the issue must have been actually litigated in the prior suit; (3) the determination of the issue in the prior litigation must have been a critical and necessary part of the judgment in that action; and (4) the party against whom the earlier decision is asserted must have had a full and fair opportunity to litigate the issue in the earlier proceeding.

RF Delaware, Inc. v. Pacific Keystone Technologies, Inc., 326 F.3d 1255, 1261 (Fed. Cir. 2003). *See also Chicago Truck Drivers, Helpers and Warehouse Union (Independent) Pension Fund v. Century Motor Freight, Inc.*, 125 F.3d 526, 530 (7th Cir. 1997). The issue in the prior litigation was not identical to the issue here because the court was not required to determine a specific conception date in order to conclude that Dr. Mahurkar had reduced his invention to practice by 1981, long before the Cook catalog came out in July 1983. The determination that Dr. Mahurkar reduced his invention to practice as early as 1981 and generally exercised reasonable diligence "[f]rom conception to filing" his patent application in October 1983 is insufficient to establish that the `984 Ash patent, filed with the PTO on December 22, 1980, cannot constitute prior art. Given the much earlier frame of reference for the alleged prior art in this case and the corroborating evidence dating only from 1981, Defendants are not collaterally estopped from arguing that the `984 Ash patent, alone or in conjunction with the `402 patent or the `631 patent, is prior art. Dr. Mahurkar's motion for summary judgment on the issue of validity of the `155 patent is denied.

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[30] The Reply Memorandum in Support of Plaintiff's Second Motion for Partial Summary Judgment on Validity of Plaintiff's `155 Patent is cited as "Pl. Validity Reply, at __."

IV. Defendants' Motion to Bar Expert Testimony and Strike Plaintiff's "Supplemental" Report

Defendants seek to bar expert testimony from Dr. Mahurkar, Ronald B. Luther, and Steve J. Schwab regarding the doctrine of equivalents, and to strike a supplemental report filed by Dr. Mahurkar on the basis that the reports do not comport with the requirements of FED. R. CIV. P. 26. Rule 26(a)(2)(B) provides that an expert report must contain, among other things, "a complete statement of all opinions to be expressed and the basis and reasons therefor; [and] the data or other information considered by the witness in forming the opinions." The discovery rules on expert witnesses "are designed to aid the court in its fact-finding mission by allowing both sides to prepare their cases adequately and efficiently and to prevent the tactic of surprise from affecting the outcome of the case." *Sherrod v. Lingle*, 223 F.3d 605, 613 (7th Cir. 2000) (construing advisory committee's note to Rule 26(a)(2)).

Pursuant to the schedule set by this court, initial expert reports were due on January 7, 2004. On that date, Dr. Mahurkar submitted four expert reports, including one from himself on the issue of infringement of the `155 and `561 patents, one from Mr. Luther on the issue of infringement of the `155 patent, and one from Dr. Schwab on the general medical background of hemodialysis and catheter technology. On February 6, 2004, Dr. Mahurkar timely served rebuttal expert reports challenging the opinions raised by Defendants' experts. The parties agreed, however, to exchange rebuttal reports from Mr. Luther and from Defendants' expert, Dr. Thomas Kinney, on February 9, 2004. Dr. Mahurkar claims that in Dr. Kinney's rebuttal report, served one day late on February 10, 2004, "Bard for the first time explained its position with respect to why Bard denies literal infringement, and pointed to alleged 'differences' between the accused catheters and the asserted claim elements." (Pl. Strike Resp., at 3-4.)[31] In response to Dr. Kinney's report,

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[31] Plaintiff's Memorandum in Opposition to Defendants' Motion to Bar Expert Testimony and Strike Supplemental Report is cited as "Pl. Strike Resp., at __."

on February 19, 2004, Dr. Mahurkar submitted a Supplemental/Rebuttal expert report on infringement to address the equivalency issues he says were newly raised in that report. Defendants insist that this is improper under Rule 26 because "a plaintiff-patentee must fully disclose his expert opinions regarding infringement in his initial report." (Def. Strike Reply, at 2)[32] (citing *Rambus, Inc. v. Infineon Technologies AG*, 145 F. Supp. 2d 721, 732 (E.D. Va. 2001) (excluding supplemental expert report submitted when "*Markman* hearing did not embrace [plaintiff's claim] construction").

A. Mr. Luther's Report

Defendants seek to bar Mr. Luther from offering an opinion as to infringement of the '155 patent under the doctrine of equivalents because his expert report does not set forth any such opinion as required by Rule 26. In his expert report, Mr. Luther makes the following statement regarding the doctrine of equivalents:

> Although I believe that Bard has literally infringed the asserted claims, I also believe that Bard infringes those claims under the doctrine of equivalents. Any possible difference between the accused products and claim elements is insubstantial, the accused catheters performing the same function, in the same way to achieve the same result. Therefore, to the extent that Bard identifies differences and contests literal infringement, I reserve the right, if I learn of new evidence or after considering Bard's expert reports which are not yet available, to testify that claims I now believe are literally infringed, are infringed under the doctrine of equivalents.

(Luther Report, Ex. C to Def. Strike Mem., ¶ 3.)[33] Later in the report, Mr. Luther states:

> Perhaps I may be misconstruing Bard's non-infringement arguments because of the lack of specificity on its interrogatory responses. Any differences between the preferred embodiment shown in the drawings and the accused products is not relevant. If Bard is relying on a bevel or imperceptible rounding at the distal end of certain of its products, then it is misapplying the patent claim elements to its accused products. In any event, I believe that any difference Bard can point to is insubstantial and hence infringement also would exist under the doctrine of

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[32] Defendants' Reply Memorandum in Support of Motion to Bar Expert Testimony and Strike Plaintiff's "Supplemental" Report is cited as "Def. Strike Reply, at __."

[33] The Memorandum in Support of Defendants' Motion to Bar Expert Testimony and Strike Plaintiff's "Supplemental" Report is cited as "Def. Strike Mem., at __."

> equivalents. However, I will withhold my final analysis until I better understand Bard's arguments so I can comment in context.

(*Id.* ¶ 29.) Finally, Mr. Luther opines that "my initial reaction by reviewing the accused products and Bard's interrogatories answers is that i[n] any event the doctrine of equivalents also establishes infringement. However, I will withhold further comment until I can better understand Bard's position." (*Id.* ¶ 37.)

Aside from reiterating the general test for equivalence, Mr. Luther provides no detail whatsoever to support his opinion that the accused catheters infringe the '155 patent under the doctrine of equivalents. Dr. Mahurkar claims that Mr. Luther could not offer such an opinion without first seeing Defendants' expert reports: "How can an expert provide a detailed explanation of differences between an accused product and a patent claim if he cannot even perceive any difference?" (Pl. Strike Resp., at 11.) Defendants respond that Mr. Luther could have made an element-by-element comparison of the products' function, way, and result to support his theory that there were no differences between them. (Def. Strike Reply, at 6.)

Even assuming it was proper for Mr. Luther to withhold a detailed analysis on the issue of infringement under the doctrine of equivalents until after he received reports from Defendants' experts, Mr. Luther never submitted any such supplemental analysis. (Def. Strike Reply, at 6.) Dr. Mahurkar insists that Defendants "ha[ve] every opportunity to probe Mr. Luther's opinions on the doctrine of equivalents . . . during his deposition." (Pl. Strike Resp., at 12.) *See* FED. R. CIV. P. 37(c) ("[a] party that without substantial justification fails to disclose information required by Rule 26(a) or 26(e)(1) . . . is not, unless such failure is harmless, permitted to use as evidence at a trial, at a hearing, or on a motion any witness or information not so disclosed"). The court concludes that Defendants' right to depose Mr. Luther does not cure the deficiency in his expert report and gives Dr. Mahurkar an unfair advantage in this litigation. Indeed, "part of the purpose of Rule 26's requirement of a detailed [expert] report is to permit the opposing party to forego the time and

expense of a deposition and instead rely on the report itself." *Berryhill v. Village of Streamwood*, No. 02 C 3268, 2004 WL 1444879, at *4 (N.D. Ill. June 28, 2004). Thus, Mr. Luther will not be permitted to offer an opinion on the doctrine of equivalents with respect to the `155 patent.

B. Dr. Schwab's Report

Like Mr. Luther, Dr. Schwab submitted an expert report that is devoid of any analysis under the doctrine of equivalents. He states that "Bard's catheters and the catheters of the `155 and `561 patents perform the same function, in the same way and both achieve the same results in hemodialysis," and that Bard's catheters "appear to have a structure which incorporate the medical and beneficial aspects described in the `155 and `561 patents." (Schwab Report, Ex. D to Def. Strike Mem., ¶¶ 25, 31.) Dr. Schwab further states that

> [s]ome of the Bard catheters accused in this lawsuit feature a bent catheter shaft that in essence accomplishes the same objectives as the bent extension tubes disclosed and claimed in the `561 patent. Moreover, it does not matter from a medical perspective if attachment of the catheter tube to the part of the catheter that connects to the dialysis machine is accomplished by bonding or is integrally formed as a single part.

(*Id.* ¶ 32.) Dr. Schwab does not, however, offer any explanation for these conclusory assertions as required by Rule 26.

Significantly, Dr. Schwab's report, which addresses the general medical background of hemodialysis and catheter technology, contains no infringement analysis and never even mentions the court's claim construction or the doctrine of equivalents. This is wholly insufficient under Rule 26 and Defendants' motion to bar Dr. Schwab from testifying on the doctrine of equivalents is granted. *See Sherrod*, 223 F.3d at 613 (the discovery rules on expert witnesses "are designed to aid the court in its fact-finding mission by allowing both sides to prepare their cases adequately and efficiently and to prevent the tactic of surprise from affecting the outcome of the case").

C. Dr. Mahurkar's Report

It is undisputed that Dr. Mahurkar's initial expert report did not discuss the doctrine of equivalents in any manner. Defendants claim that his additional report, filed on February 19, 2004, is not a proper "supplemental" report under Rule 26(e) because it is based on information that was available to Dr. Mahurkar prior to his initial report. (Def. Strike Mem., at 8) (citing *Collier v. Bradley Univ.*, 113 F. Supp. 2d 1235, 1242 (C.D. Ill. 2000)) (striking supplemental expert report that "constitute[d] a belated attempt to add theories to her opinion that were never before identified or discussed in any substantive manner"). Dr. Mahurkar argues that he could not offer an opinion on equivalence because it was not until he received Dr. Kinney's report that he knew the differences alleged by Defendants. (Pl. Strike Resp., at 7-8.) The court finds this argument suspect given that Dr. Mahurkar bears the burden of proving infringement under the doctrine of equivalents. Moreover, he has not offered any logical explanation for his claimed inability to detail exactly why the patented catheters and the accused devices are no different from each other without first learning the ways in which Defendants say they are different.

Nevertheless, any potential prejudice or harm arising from the late report can be cured by allowing Defendants to file an additional report responding to Dr. Mahurkar's new opinions. *See, e.g., Carter v. Finely Hosp.*, No. 01 C 50468, 2003 WL 22232844, at *2 (N.D. Ill. Sept. 22, 2003) (setting forth four factors to consider in determining whether party had substantial justification for failing to comply with Rule 23(e), including prejudice to the other side and ability to cure that prejudice). Dr. Mahurkar does not object to such an allowance, even if it means postponing the trial date. (*See* Pl. Strike Resp., at 2 and 7 n.7). Thus, Defendants' motion to strike Dr. Mahurkar's supplemental report is denied, but they have until October 15, 2004 to submit a responsive report.

CONCLUSION

For the reasons stated above, Defendants' Motion for Summary Judgment of Noninfringement of the `561 Patent (Docket No. 180-1) is granted on the issue of literal infringement as to the Softcell, Optiflow, Hemoglide, Niagara, and Niagara SlimCath catheters; denied on the issue of infringement of the Softcell, Optiflow, Hemoglide, Niagara, and Niagara SlimCath catheters under the doctrine of equivalents; and denied in its entirety as to the Flexxicon II catheters. Plaintiff's Motion for Summary Judgment on Literal Infringement of the `561 Patent (Docket No. 223-1) is denied.

Plaintiff's Motion for Summary Judgment on Defendants' Licensee Affirmative Defense (Docket No. 166-1) is granted but his Motion for Summary Judgment on Defendants' Invalidity Defense to the `155 Patent (Docket No. 169-1) is denied. Defendants' Motion to Bar Expert Testimony (Docket No. 187-1) is granted but their Motion to Strike Plaintiff's "Supplemental" Report (Docket No. 187-2) is denied. Defendants' supplemental expert report is due October 15, 2004.

ENTER:

Dated: September 7, 2004

REBECCA R. PALLMEYER
United States District Judge

EXHIBIT A

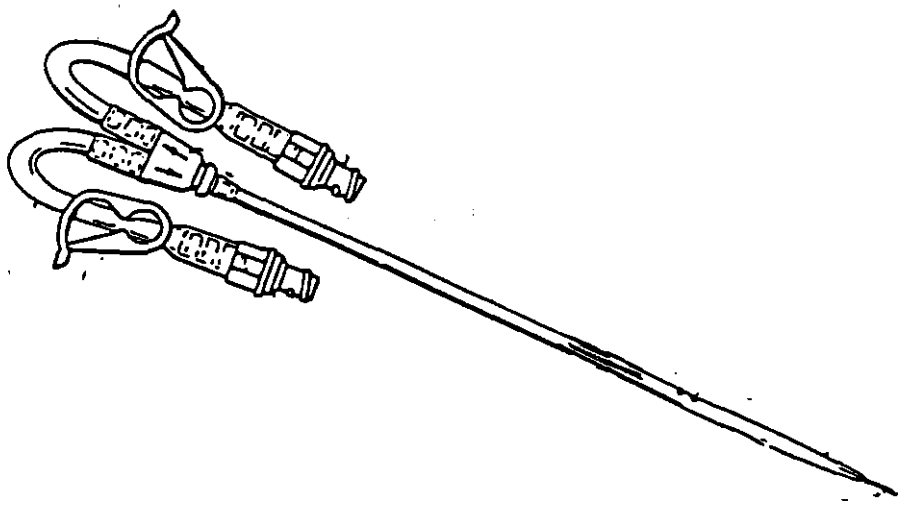

EXHIBIT B

Niagara

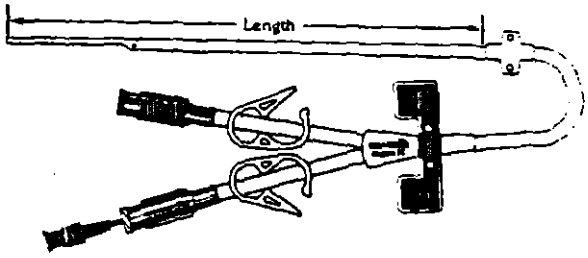

EXHIBIT C

Flexxicon II